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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,887

05/24/2006

Yatendra Kumar

RLL-298US

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EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,887	Applicant(s) KUMAR ET AL.	
	Examiner Susannah Chung	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/24/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-21 are pending in the instant application.

Priority

This application is a 371 of PCT/IB03/04873, filed 10/31/2003.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) by application no. 1095/DEL/2002 filed in the Indian Patent Office on 10/31/2002, which papers have been placed of record in the file. The application names an inventor or inventors named in the prior application.

Information Disclosure Statement

The information disclosure statement (IDS), filed on 05/24/2006 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are incomplete because they omit essential steps, such omission amounting to a gap between the steps. See MPEP §2172.01. The omitted steps are the reagents used and specific steps of preparing the amorphous losartan potassium. Applicants need to include specific reagents and steps as described in the specification on page 6.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims must stand alone to define the invention and incorporation into claims by express reference to the specification is not permitted. *Ex parte Fressola*, 27 USPQ 2d 1608. Claims that require one to read the specification to determine the metes and bounds of the invention are repugnant to modern practice in the Office and are properly rejected under 35 USC 112, 2nd paragraph, as failing to particularly point out and distinctly claim the invention. *Id.* At 1609. Therefore, any references to tables and figures should be incorporated into the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being obvious over Carini et al (US Patent No. 5,138,069 ('069 Pat) in view of Campbell et al (US Patent No. 5,608,075 ('075 Pat).

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Applicants claims relate to amorphous losartan potassium.

Determination of the scope and content of the prior art (MPEP § 2141.01)

Losartan potassium, also known as 2-butyl-4-chloro-1-[[2'-(1H-tetrazol-5-yl)[1,1'-biphenyl]-4-yl]-1H-imidazole-5-methanol monopotassium salt, is a competitive AT2 angiotensin II receptor antagonist.

Carini, et al. teach the compound and process of making losartan potassium. (See '069 Pat, Columns 264-280, claims 1-39, and claim 18 in particular.)

Campbell, et al. teach the compound and process of making losartan potassium and forms (I) and (II). The x-ray diffraction pattern and IR data of the specific forms are taught. (See '075 Patent, Columns 11-13 in particular.)

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between the prior art of Carini and the instant claims is that the prior art is silent as to the characteristics, i.e. x-ray diffraction pattern, of amorphous losartan potassium.

The difference between the prior art of Campbell and the instant claims is that the prior art specifically claims form (I) and (II) of losartan potassium.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

However, in the absence of showing unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention when faced with Carini and Campbell that amorphous losartan potassium could be made with the instantly claimed specifications. Carini and Campbell do not explicitly disclose the x-ray diffraction pattern and other data as the instant claims to, but that does not mean that the amorphous form of Carini and Campbell did not have the same properties as instantly claimed.

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It is well known in the art that an amorphous solid is a solid in which there is no long-range order of the positions of the atoms, unlike crystalline solids. It is invariable found that the amorphous form of a compound is less stable than its crystalline modification, in the sense that the amorphous form tends to crystallize spontaneously, indicating its instability. See Brittain, Polymorphism in Pharmaceutical Solids, Vol. 95, 1999, page 305. Therefore, the crystalline forms are more stable and easier to characterize.

Guided by the teachings of Carini and Campbell one of ordinary skill in the art would be able to make similar amorphous losartan potassium derivatives claimed in the instant claims. The motivation would be to prepare similar compounds that are pharmacologically active compounds that act as angiotensin 2 receptor antagonists.

The instant obviousness rejection is based on the close structural similarity of the instantly claimed compounds to the prior art compounds and the common utility shared among the compounds. There is an expectation among those of ordinary skill in the art that similar structural compounds will have similar properties and that modification of a known structure is mere experimentation within the means of a skilled artisan. See MPEP 2144.09(I). Therefore, the claims are rejected as obvious over the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being obvious over Campbell et al (US Patent No. 5,608,075 ('075 Pat) in view of Breen et al. (US Pat No. 5,859,258 ('258 Pat)).

Applicants claims relate to a process of making amorphous losartan potassium.

Determination of the scope and content of the prior art (MPEP § 2141.01)

Campbell, et al. teaches the compound and process of making losartan potassium and forms (I) and (II). (See '075 Patent, Columns 26, claims 9-11 in particular.)

Breen, et al. teaches the compound and process of making losartan potassium. (See '258 Patent, Columns 8-10, claims 1-8 in particular.)

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between the prior art and the instant claims is that the prior art specifically claims and teaches processes of making losartan potassium including reagents used, temperatures and process steps, while the instant claims are broader.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

However, in the absence of showing unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention when faced with the prior art to make the instantly claimed process

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The selection of reaction conditions is more optimization by more modification of routine experimentation and within one skilled in the art. Changes in temperature, concentration, or both is not patentable modification in the absence of unexpected results which is different in kind and not degree. In re Aller, 105 USPQ 233.

Discovery of an optimum value of a result effective variable is not patentable if such discovery is within one skilled in the art. A prima facie case of obviousness may be rebutted in optimizing a variable only when results are unexpectedly good. In re Boesch, 205 USPQ 215.

The instant obviousness rejection is based on the close process steps, i.e. reagents used, starting materials, temperature, etc...

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Golam M. M. Shameem/

Primary Examiner, Art Unit 1626

Susannah Chung, 2/15/2009